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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NEW YORK, NY 10016				
EXAMINER				
RAO, SAVITHA M				
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1629				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,676

Applicant(s)

SCHRAMM ET AL.

Examiner

SAVITHA RAO

Art Unit

1629

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/14/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☐ Claim(s) ____ is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☐ Claim(s) ____ is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 1-13, 19, 27, 35, 41, 45, 46 and 48 are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-C100)
- Paper No(s)/Mail Date ____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-13, 19, 27, 35, 41, 45-46 and 48 are currently pending in the instant application and are subject to a lack of unity requirement.

Election Restrictions

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Group I: Claims 1-2 and 7-12 drawn towards a compound of formula (I)

Please note additional Election of Species Requirement outlined below.

II. Group II : Claims 1, 3 and 7-12 drawn towards a compound of formula (II)

Please note additional Election of Species Requirement outlined below.

III. Group III : Claims 1, 4 and 7-12 drawn towards a compound of formula (III)

Please note additional Election of Species Requirement outlined below.

IV. Group IV : Claims 1, 5 and 7-12 drawn towards a compound of formula (IV)

Please note additional Election of Species Requirement outlined below.

V. Group V : Claims 1, 6 and 7-12 drawn towards a compound of formula (V)

Please note additional Election of Species Requirement outlined below.

VI. Group VI : Claims 13, 19, 35, 41 and 45 drawn to a method of inhibiting base exchange more than deacetylation of an acetylated peptide by a SIR2 enzyme, the method comprising combining the compound of **Group I** above with the SIR2 enzyme, NAD⁺ and the acetylated peptide. , **Please note additional Election of Species Requirement outlined below.**

VII. Group VII : Claims 13, 19, 35, 41 and 45 drawn to a method of inhibiting base exchange more than deacetylation of an acetylated peptide by a SIR2 enzyme, the method comprising combining the compound of **Group II** above with the SIR2

enzyme, NAD⁺ and the acetylated peptide. **Please note additional Election of Species Requirement outlined below.**

VIII. Group VIII : Claims 13, 19, 35, 41 and 45 drawn to a method of inhibiting base exchange more than deacetylation of an acetylated peptide by a SIR2 enzyme, the method comprising combining the compound of **Group III** above with the SIR2 enzyme, NAD⁺ and the acetylated peptide. **Please note additional Election of Species Requirement outlined below.**

IX. Group IX : Claims 13, 19, 35, 41 and 45 drawn to a method of inhibiting base exchange more than deacetylation of an acetylated peptide by a SIR2 enzyme, the method comprising combining the compound of **Group IV** above with the SIR2 enzyme, NAD⁺ and the acetylated peptide. **Please note additional Election of Species Requirement outlined below.**

X. Group X : Claims 13, 19, 35, 41 and 45 drawn to a method of inhibiting base exchange more than deacetylation of an acetylated peptide by a SIR2 enzyme, the method comprising combining the compound of **Group V** above with the SIR2 enzyme, NAD⁺ and the acetylated peptide. **Please note additional Election of Species Requirement outlined below.**

XI. Group XI: Claims 27 is drawn to a method of A method of increasing protein deacetylation by a SIR2 enzyme in a living cell, the method comprising combining the cell with the compound of **Group I** above. **Please note additional Election of Species Requirement outlined below.**

XII. Group XII : Claim 27 is drawn to a method of A method of increasing protein deacetylation by a SIR2 enzyme in a living cell, the method comprising combining the cell with the compound of **Group II** above. **Please note additional Election of Species Requirement outlined below.**

XIII. Group XIII : Claim 27 is drawn to a method of A method of increasing protein deacetylation by a SIR2 enzyme in a living cell, the method comprising combining the cell with the compound of **Group III** above. **Please note additional Election of Species Requirement outlined below.**

XIV. Group XIV : Claim 27 is drawn to a method of A method of increasing protein deacetylation by a SIR2 enzyme in a living cell, the method comprising combining the cell with the compound of **Group IV** above. **Please note additional Election of Species Requirement outlined below.**

XV. Group XV : Claim 27 is drawn to a method of A method of increasing protein deacetylation by a SIR2 enzyme in a living cell, the method comprising

combining the cell with the compound of **Group V** above. **Please note additional Election of Species Requirement outlined below.**

XVI. Group XVI : Claim 46 and 48 is drawn to a method of screening a test compound for the ability to increase SIR2 deacetylation activity, the method comprising combining the test compound of **Group I** above with the SIR2 enzyme, NAD⁺ and an acetylated peptide substrate of SIR2 in a reaction mixture, and determining whether the compound prevents base exchange more than deacetylation. . **Please note additional Election of Species Requirement outlined below.**

XVII. Group XVII : Claim 46 and 48 is drawn to a method of screening a test compound for the ability to increase SIR2 deacetylation activity, the method comprising combining the test compound of **Group II** above with the SIR2 enzyme, NAD⁺ and an acetylated peptide substrate of SIR2 in a reaction mixture, and determining whether the compound prevents base exchange more than deacetylation. . **Please note additional Election of Species Requirement outlined below.**

XVIII. Group XVIII : Claim 46 and 48 is drawn to a method of screening a test compound for the ability to increase SIR2 deacetylation activity, the method comprising combining the test compound of **Group III** above with the SIR2 enzyme, NAD⁺ and an acetylated peptide substrate of SIR2 in a reaction mixture, and determining whether the

compound prevents base exchange more than deacetylation. . **Please note additional Election of Species Requirement outlined below.**

XIX. Group XIX : Claim 46 and 48 is drawn to a method of screening a test compound for the ability to increase SIR2 deacetylation activity, the method comprising combining the test compound of **Group IV** above with the SIR2 enzyme, NAD⁺ and an acetylated peptide substrate of SIR2 in a reaction mixture, and determining whether the compound prevents base exchange more than deacetylation. . **Please note additional Election of Species Requirement outlined below.**

XX. Group XX : Claim 46 and 48 is drawn to a method of screening a test compound for the ability to increase SIR2 deacetylation activity, the method comprising combining the test compound of **Group V** above with the SIR2 enzyme, NAD⁺ and an acetylated peptide substrate of SIR2 in a reaction mixture, and determining whether the compound prevents base exchange more than deacetylation. . **Please note additional Election of Species Requirement outlined below.**

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Since in the instant application the claims are drawn to several patentably distinct inventions, based on, products and methods of use as shown above, and according to 37 CFR 1.475(e): the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the

inventions are claimed in separate claims or as alternatives within a single claims.

The claims, therefore, lack unity of invention as there is no common technical feature linking the various groups listed above and there are twenty different groups.

As such the inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Groups I-XX are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept, and therefore, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

1. Specie election 1: This specie election applies to Groups I-XX detailed in the restriction requirement above. Upon electing any of the group above, applicant is required to elect single disclosed specie of the compound of formula wherein every variable in the structure above is clearly defined. Claims 1-13, 19, 27, 35, 41, 45-46 and 48 are generic to these species. For example, Fluronicotinamide recited in instant claim 9.

The species are structurally divergent, differ in their physical, chemical and biological properties and activities and thereby require searching in different

class/subclasses and use of different search queries. Additionally, the different properties of the claimed species would also result in different efficacies and bioavailability profiles

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Lundgren can be reached at 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1629

